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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,978

09/15/2006

David I. Cohen

51311-00009

2811

45200 7590 02/18/2010  
K&L Gates LLP  
1900 MAIN STREET, SUITE 600  
IRVINE, CA 92614-7319

EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

02/18/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ocipgroup@klgates.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/598,978	<b>Applicant(s)</b> COHEN, DAVID I.	
	<b>Examiner</b> STUART W. SNYDER	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/25/2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Specification*

1. Objection to the disclosure because of inadequate reference to “hatched” portions of figures 10-12 is **withdrawn** in view of Applicants’ amendment of the Specification.
2. Objection to the disclosure because of inadequate reference to Figures 16A and 16B is **withdrawn** in view of Applicants’ amendment of the Specification.

### *Claim Rejections - 35 USC § 112*

3. Rejection of Claims 1-5 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is **withdrawn** in view of Applicants’ amendment of Claim 1.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Rejection of Claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Cohen, Cohen, et al., Cheadle, et al., and Baghian, et al. is maintained for reasons of record and those below.

Applicants traverse the rejection by alleging the claimed method differs from the Art cited in the prior Office action mailed 3/5/3009 by requiring determination of both dendritic cells (DCs) and regulatory macrophages (AReg) in the instantly

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claimed subject matter whereas the cited art teaches only determination of immunosuppressive AReg and not DC.

The Examiner does not dispute the difference in the teaching of the cited art but respectfully disagrees with the claim interpretation by Applicants. The Examiner asserts that literal interpretation of steps e and f of claim 1 does not require the measurement of both AReg and DC. The relevant section of claim 1 is reproduced below:

- e. incubating said test culture to allow said monocytes to differentiate into dendritic cells (DC) **or** regulatory macrophages (AREg);
- f. removing said differentiated cells from said test culture and determining the presence of DCs **or** AReg in the differentiated cell population;  
wherein the relative presence of DCs and/**or** AReg identifies an immunosuppressive NICE or an immunostimulatory NICE.

The Examiner has highlighted the relevant language; reference to DC and AReg is always in the alternative. The method for identifying NICE requires allowing the monocytes to differentiate into DC **or** AReg, determining the presence of DCs **or** AReg, and identification of the nature by determining the relative presence of DCs **or** AReg. Ordinary and customary interpretation of the phrase “and/or” in the context of the claim would be that “the relative presence of DCs **or** AReg” and “the relative presence of DCs and AReg” are equally valid meanings of the phrase as a whole. Thus, the claim does not require determination of DC and AReg. Therefore, the art cited by the Examiner teaches the instantly claimed

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method and the claims are properly rejected as obvious over Cohen, Cohen et al., Cheadle, et al., and Baghain.

***Conclusion***

5. No claims are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/  
Primary Examiner, Art Unit 1648

Stuart W Snyder  
Examiner  
Art Unit 1648

SWS